MANEUVERABLE OPTICAL FIBER DEVICE FOR CARDIAC PHOTOABLATION

Field of the Invention

The present invention is directed to systems and methods for ablating interior regions of the heart for treatment of cardiac abnormalities.

Background Of The Invention

Treatment of tissues generally requires direct contact of the target tissue with a medical instrument, usually by a surgical procedure which exposes both the target and intervening tissue to substantial trauma, e.g. bleeding and/or infection. Often, precise placement of a treatment probe is difficult due to the location of a target tissue in the body or proximity of the target tissue to easily damaged critical body organs, nerves, or other physiological components.

Destruction of cellular tissues *in situ* has been used in the treatment of diseases and medical conditions alone or as an adjunct to surgical removal procedures. These methods are often less traumatic than surgical procedures alone and may be the only alternative where surgical procedures are determined to be unsafe. Ablative treatment devices have the advantage of using a destructive energy which rapidly dissipates and is reduced to a non-destructive level by conduction and/or convection forces of circulating fluids and other natural physiological processes.

For example, microwave, radio frequency, acoustical (ultrasound), in light energy (laser) devices and tissue destructive substances have been used to destroy malignant, benign and other types of aberrant cells in tissues from a wide variety of anatomical sites and organs. Tissues sought to be treated include isolated carcinoma masses and, more specifically, organs such as the prostate, bronchial passage ways, passage ways to the

bladder, passage ways to the urethra, and various passage ways into the thoracic area, e.g., the heart.

Devices useful for the treatment of such disease states or conditions typically include a catheter or an cannula which can be used to carry a radio frequency electrode or a microwave antenna through a duct to the zone of treatment. An energy is applied through the duct wall into the surrounding tissue in all directions, thereby destroying the diseased tissue, and oftentimes surrounding tissue.

Steerable catheters are known for use in a variety of medical procedures. See, for example, U.S. Patent Nos. 4,998,916 to Hammerslag, 4,960,134 to Webster, Jr., 4,753,223 to Bremer, 4,685,457 to Donenfeld, 3,605,725 to Bentov, 3,470,876 to Barchilon, 4,944,727 to McCoy and 4,838,859 to Strassman. These catheters employ one or a plurality of steering wires which extend from a steering mechanism at the proximal end of the catheter to an anchor point at the distal end of the catheter. By manipulating the individual steering wires using the control mechanism, the tip of the catheter can be manipulated in a desired direction. In addition to being steerable in the lateral direction, further positioning of known catheters is accomplished by rotating the catheter as a whole about its longitudinal axis, typically by turning or twisting the proximal end of the catheter. This action exerts a torque along the length of the catheter which is translated into a rotational motion at the distal end which allows a laterally deflected distal tip to be rotated.

U.S. Patents 5,454,794, 5,441,497, 5,269,777 and 5,267,995 describe alternative embodiments of steerable catheters. For example, the catheters may include a flexible tip suitable for the transmission of light and dimensioned to pass through extremely small tubular members. The flexible tip, preferably made of optically transparent silicone elastomer, is affixed to the terminal end of a conventional optical fiber. In a preferred embodiment, the flexible tip includes a central silicone core surrounded by a cladding having an index of refraction less than that of the core which permits internal reflection. The flexible tip is provided with an outer jacket for providing structural integrity for the tip

and reinforcing the union between the flexible tip and the optical fiber to which it is abutted. The tip has the flexibility to be able to enter tortuous tubular members while retaining the light transmitting capabilities of relatively inflexible glass optical waveguides of the same diameter.

Careful and precise control over the catheter is required during critical procedures which heat tissue within the heart. Such procedures are termed "ablation" therapy and are becoming widespread for treatment of cardiac rhythm disturbances. During these procedures, an operator guides a catheter through a main artery or vein into the interior of the heart which is to be treated. The operator manipulates a mechanism to cause an electrode which is carried on the distal tip of the catheter into direct contact with the tissue area to be treated. Energy is applied from the electrode into the tissue and through an indifferent electrode (in a uni-polar electrode system) or to an adjacent electrode (in a bi-polar electrode system) to ablate the tissue and form a lesion.

Cardiac mapping can be used prior to ablation to locate aberrant conductive pathways within the heart. The aberrant conductive pathways are called arrhythmias. Mapping of the heart identifies regions along these pathways, termed "foci", which are then ablated to treat the arrhythmia.

Currently, guidewires (pullwires) are used to direct catheters in a body lumen have several disadvantages. Guidewires have a tendency to break or release from the point of attachment in a catheter. Guidewires are generally not formed from the same material as the catheter body and therefore are not readily permanently affixed to the catheter body; hence the guidewire can inadvertently release. Another disadvantage of current guidewires is that they are often heated by an energy source within the catheter during a treatment and transfer heat to areas away from the treatment site. Most guidewires are opaque and can be problematic in directing a catheter and locating the catheter to the proper treatment site.

As described above, there are drawbacks with many of the currently available catheters. Oftentimes it is difficult, if not impossible, to maneuver the instrument into small passage ways, such as a ventricle, without damaging the surrounding tissue. Additionally, directing the ablative energy onto the tissue site to be treated can be problematic, especially when vital organs surround the diseased tissue. Therefore, it would be desirable to direct ablative energy onto a specific treatment area wherein surrounding tissue is not degraded.

Summary Of The Invention

The present invention circumvents the problems described above by delivering energy, e.g., laser light or other ablating energy, in a linear region thereby avoiding damage to surrounding tissues. In a particular embodiment, the apparatus of the invention includes a reflective material which concentrates the energy onto or into a specific target site. The present invention thus provides instruments and methods for percutaneous catheter ablation of diseased, necrotic, or aberrant tissue cells with minimal or no degradation of tissue surrounding these target sites. Patients may therefore not require pharmacological or surgical therapy, thus reducing the morbidity and expense of therapy.

The invention provides a device and method for tissue destruction of body tissues which delivers therapeutic energy directly into a target tissue while minimizing effects on the surrounding tissue. In a preferred embodiment, the therapeutic energy is phototherapeutic radiation.

This invention is directed to a unique device and method for steering a catheter into body tissues, e.g., chambers of the heart, for medical purposes such as tissue destruction. Therefore the device limits the delivered energy to the precise preselected site, thereby minimizing trauma to adjacent surrounding tissue and achieving an enhanced medical benefit. The present invention is a catheter-like device for positioning a treatment

assembly in the area or organ selected for medical treatment and includes one or more deflection members mounted within the catheter for positioning catheter within the preselected body cavity.

The present invention is based, at least in part, on the discovery that attachment of a polymeric, tubing like deflection member to the distal end of a flexible elongate member, e.g. a catheter, provides a means to bend, distort, or deform the flexible elongate member to a desired position. As a consequence of this maneuverability, an energy beam can be directed onto/into a specific target site, e.g., an anatomically important region, for treatment. A preferred method is by phototherapeutic radiation.

An important advantage of the deflection members of the invention centers on the compatibility of the deflection member with the catheter body. The deflection member is typically constructed from the same or similar material as that of the catheter, thereby providing an integral match at attachment point(s). "Welding" of the deflection member to the catheter body provides an integral bond between the two members so that detachment does not occur. Additionally, as the deflection member is constructed from a polymeric material, heat is not appreciably transferred away from an anatomically important region to a site which does not require such treatment. In certain applications it may also be desirable to employ the present invention in tandem with conventional (e.g., pull wire-type) steering mechanisms. For example, the cut-away structures of the present invention can facilitate flexure in a predefined direction while the pull wire or other steering mechanism provides most, if not all, of the bending force.

The present invention is drawn to an apparatus for inducing hyperthermia, coagulation and/or phototherapeutic processes in tissue, preferably by phototherapeutic radiation. The apparatus includes a flexible elongate member, a deflection member, a control handle, a conductor and an energy source. The flexible elongate member has a proximal end, a distal end, and a longitudinal first lumen which extends between the

proximal end and the distal end. The deflection member is fixedly attached to the distal end of the elongate member and has a proximal end and a distal end. The control handle is mounted at the proximal end of the apparatus including the deflection member and is used for tensing the deflection member longitudinally, relative to the elongate member, thereby causing the distal end of the elongate member to bend, distort or deform. The conductor extends along and within the first lumen for transmitting energy to or near the distal region, e.g., end, of the elongate member. The energy source is in communication with the proximal end of the conductor and is effective to transmit energy through the conductor. A typical energy source provides a source of energy such as microwave, or ultrasound energy. In a preferred embodiment, the energy is laser energy.

The invention is also directed to methods for ablating, coagulating, and/or phototherapeutically modulating a target tissue. The methods include introducing a flexible elongate member into a predetermined tissue site with a flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween. A deflection member is fixedly attached to the distal end of the elongate member and includes a proximal end and a distal end. The deflection member is manipulated longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend. A slidable conductor is positioned through the lumen proximate to the tissue site and energy is transmitted to the distal region of the elongate member through the conductor. The target tissue is ablated, coagulated and/or phototherapeutically modulated without damaging surrounding tissue. In one embodiment, the energy is transmitted through an energy transparent flexible elongate member. In another embodiment the energy is laser light. In still another embodiment, the energy is directed toward the target tissue by reflection from a reflective material behind or in front of the deflection member and/or the conductor.

The invention is further directed to methods for treating trabecular tissue by ablation, coagulation and/or phototherapeutic processes. The methods include introducing

a flexible elongate member proximate to trabecular tissue with the flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween. A deflection member is fixedly attached to the distal end of the elongate member and includes a proximal end and a distal end. The deflection member is manipulated longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend, distort, or deform. A conductor is slidably positioned within the lumen, proximate to the trabecular tissue site. Energy is transmitted to the distal end of the elongate member through the conductor, such that the trabecular tissue is ablated, coagulated and/or phototherapeutically modulated without damaging surrounding tissue. The treatment can be performed prophylactically or therapeutically.

The present invention is also directed to methods for treating or preventing atrial fibrillation by ablation, coagulation and/or phototherapeutic processes. The methods include introducing a flexible elongate member proximate to atrial tissue with the flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween. A deflection member is fixedly attached to the distal end of the elongate member and includes a proximal end and a distal end. The deflection member is manipulated longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend, distort, or deform. A conductor is slidably positioned within the lumen, proximate to the atrial tissue site. Energy is transmitted to the distal end of the elongate member through the conductor, such that the atrial tissue is ablated, coagulated and/or phototherapeutically modulated without damaging surrounding tissue. The treatment can be performed prophylactically or therapeutically.

Brief Description Of The Drawings

Other objects, advantages and features of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed

description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 is a cross-section view of a steerable catheter of an embodiment of the invention having a deflection member affixed to the outer flexible elongate member and including a conductor disposed within the lumen of the flexible elongate member;

FIG. 2 is a cross-section view of the catheter body taken along the lines 2-2 of FIG. 1;

FIG. 3 is a front elevation view of a steerable catheter of the present invention including a deflection member and a conductor located within the lumen of the flexible elongate member;

FIG. 4 is a cross-section view of a catheter of the invention having a unitary solid deflection member attached to the flexible elongate member and including a conductor located within the lumen of the flexible elongate member;

FIG. 5 is a cross-section view of the catheter body taken along lines 5-5 of FIG. 4;

FIG. 6 is a front elevation view of a steerable catheter of the invention including a unitary solid deflection member fixedly attached to the flexible elongate member having a conductor located within the lumen of the flexible elongate member;

FIG. 7 is a cross-section view of a steerable catheter of the invention having two deflection members fixedly attached to the flexible elongate member and a conductor located within the lumen formed by the two deflection members and the flexible elongate member;

FIG. 8 is a cross-section view of the catheter body taken along lines 8-8 of FIG. 7;

FIG. 9 is a front elevation view of a steerable catheter of the invention having two deflection members fixedly attached to flexible elongate member and having a conductor located within the lumen formed by the flexible elongate member and the deflection members;

FIG. 10 is a cross-section view of a steerable catheter of the invention having an hourglass-like deflection member fixedly attached to one side of the flexible elongate member and a conductor located within the lumen formed by the hourglass shaped deflector member and/or the flexible elongate member;

FIG. 11 is a front elevation view of a steerable catheter of the invention having an hourglass shaped deflection member fixedly attached to the flexible elongate member having a conductor located within the lumen formed by the flexible elongate member and/or the hourglass shaped deflector;

FIG. 12 is a cross-section view of a steerable catheter the invention having a tapered deflection member fixedly attached to the flexible elongate member and a conductor located within the lumen formed by the tapered deflection member and/or the flexible elongate member;

FIG. 13 is a cross-section view of the catheter body taken along lines 13-13 of FIG. 12;

FIG. 14 is a front elevation view of a steerable catheter of the invention having a tapered deflection member fixedly attached to the flexible elongate member and a conductor located within the lumen formed by the flexible elongate member and/or the tapered deflection member;

FIG. 15 is a cross-section view of a steerable catheter of the invention having a deflection member which has a portion removed proximate to the distal end of the deflection member and a conductor located within the lumen formed by the deflection member and/or flexible elongate member;

FIG. 16 is a cross-section view of the catheter body taken along lines 16-16 of FIG. 15;

FIG. 17 is a front elevation view of a steerable catheter of the invention having a partially cut away deflection member fixedly attached to the flexible elongate member and a conductor located within the lumen formed by the cut away deflection member and/or the flexible elongate member;

FIG. 18 is a cross-section view of a steerable catheter of the invention having a reflective material attached to the flexible elongate member, a cut away deflection member fixedly attached to the flexible elongate member which is proximate to the reflector material and a conductor positioned in front of both the reflector material and the cut away deflection member, located in the lumen formed by the flexible elongate member and/or the cut away deflection member;

FIG. 19 is a cross-section view of the catheter body taken along lines 19-19 of FIG. 18;

FIG. 20 is a front elevation view of a steerable catheter of the invention having a reflective material attached to the flexible elongate member and a cut away deflective member fixedly attached to the flexible elongate member which is proximate to the reflective material, and a conductor located within the lumen formed by the flexible elongate member and/or the cut away deflective member;

FIG. 21 is a cross-section view of a steerable catheter having a deflective member fixedly attached to the flexible elongate member and a reflective material positioned apart from the deflective member, and a conductor located within the lumen formed by the flexible elongate member, or the deflective member and/or reflective material;

FIG. 22 is a cross-section view of the steerable catheter body taken along lines 22-22 of FIG. 21;

FIG. 23 is a front elevation view of a steerable catheter of the invention having a deflection member fixedly attached to the flexible elongate member, a reflective material attached to the flexible elongate member apart from the deflective member and a conductor located within the lumen formed by the flexible elongate member, the deflective material, and/or the reflective member;

FIG. 24 is a cross-section view of a steerable catheter of the invention having a deflection member which is cut away is a helical configuration;

FIG. 24 A is a cross-section view of the steerable catheter of FIG. 24 at position A;

FIG 24 B is a cross-section view of the steerable catheter of FIG. 24 at position B;

FIG 24 C is a cross-section view of the steerable catheter of FIG. 24 at position C;

FIG. 25 is a cross-section view of a steerable catheter of the invention having a deflection member which includes cut away sections which are opposed relative to each other;

FIG 25 A is a cross-section view of the steerable catheter of FIG. 24 at position A;

FIG 25 B is a cross-section view of the steerable catheter of FIG. 24 at position B;

FIG 25 C is a cross-section view of the steerable catheter of FIG. 24 at position C;

FIG 25 D is a cross-section view of the steerable catheter of FIG. 24 at position D;

FIG. 26 is a cross-sectional view of a steerable catheter having multiple weld sites for multiple deflection members, thereby allowing control in any x, y, or z planes;

FIG. 27 shows application of an apparatus of the invention applied to an atrial wall and having a conductor positioned within the inner lumen of the flexible elongate member;

FIG. 28 is a cross-sectional view of a steerable catheter having at least two deflection members which are slidably connected via male/female connectors;

FIG. 29 is a schematic block diagram of a laser tissue treatment system according to the present invention; and

FIG. 30 is a detailed schematic diagram of a reflectance monitor for use in the present invention.

Detailed Description Of The Invention

The features and other details of the invention will now be more particularly described and pointed out in the claims. It will be understood that the particular embodiments of the invention are shown by way of illustration and not as limitations of the invention. The principle features of this invention can be employed in various embodiments without departing from the scope of the invention.

The present invention is based, at least in part, on a discovery that the present invention can be used for inducing hyperthermia, coagulation and/or phototherapeutic processes in tissue, e.g., ablation, degradation, or destruction of tissue, at a specified site in tissue without harming the surrounding tissue. The apparatus includes a flexible elongate member, one or more deflection members, a control handle, a conductor and an energy source. The flexible elongate member has a proximal end, a distal end and a longitudinal first lumen which extends between the proximal and distal ends of the flexible elongate member. The deflection member is fixedly attached to the distal end of the elongate member and has a proximal and distal end. The control handle is mounted at the proximal end of the deflection member(s) and is used for tensing the deflection member longitudinally relative to the elongate member which causes the distal end of the elongate member to bend, distort, or deform. The conductor extends along and within the first lumen and transmits energy to the distal end of the elongate member. The energy source is in communication with the proximal end of the conductor and is effective to transmit energy through the conductor. The apparatus is a steerable and positionable flexible catheter-like device. Those skilled in the art may refer to the apparatus as a catheter.

The term "phototherapeutic" is intended to include photochemical and photothermal processes which are therapeutic and/or prophylactic in a subject.

The terms "ablate" or "ablation" or "photothermal" are well recognized in the art and are intended include to thermal coagulation and/or removal of tissues which are necrotic, damaged, or are aberrant in nature. Ablation also includes the desiccation of tissue by the application of heat. For example, an ablating energy, such as those described above, would be one that would cause the tissue to reach a temperature of between about 60 to 90° C. Ablation increases the physiological temperature of a tissue by energetic stimulation to a temperature which degrades or eradicates tissue, thereby removing diseased tissue from a localized area. Ablation can be used as a therapeutic treatment, where diseased or otherwise unwanted tissue or cells exist, or as a preventative treatment to

inhibit growth of undesirable tissue or cells in a specific region of an organ or viscera. In order to obtain destruction of tissue exclusively by thermal effects, it is necessary for the energy to be able to reach a threshold of destruction referred to as the "thermal dose". This threshold is a function of temperature reached and of the duration of the application. Therefore, ablation, to some degree, is based on the rise of the local temperature of tissue.

The term "coagulation" is well recognized in the art and is intended to mean the action whereby cells and/or body fluids within a treated tissue site are caused to become necrosed, thickened and/or lose the ability to conduct electrical activity, thereby resulting in a coherent mass by the methods of the invention. The method and apparatus of the invention permit selective, coagulation of a targeted tissue area and not blood or other body fluids which are found external, e.g., surrounding, to the target site.

The term "photochemical" is well recognized in the art and includes various energetic processes, including chemical reactions initiated by photons generated by an energy source. Typically photochemical processes are associated with laser, ultra-violet light, visible light or infrared light. Photochemical processes include the generation of radicals by photons colliding with tissue. The radical species are generated within cell tissue, often times causing oxidation of the cell contents; degradation or eradication occurs after the radical species are generated.

Photochemical processes cause injury to cells and tissue either by mechanical lysis or by the generation of by products such as free radicals, e.g., such as $HO_2\bullet$, $OH^-\bullet$, $HO\bullet$ and $H_2O\bullet$, which damage the cell membrane. These reactive by products can interact with the localized surrounding tissue area such that the tissue is cleansed of unwanted material. Photochemical processes can involve oxidation or radical polymerization of, for example, cell walls, extracellular matrix components, cell nuclei, etc. Such photochemical processes are induced by ultraviolet, laser and far infrared energy.

The terms "into" and "onto" are used interchangeably and are intended to include treatment of tissue by directing energy toward the afflicted area. In some instances the energy penetrates the tissue and in other instances the energy only superficially treats the surface of the tissue. An ordinary skilled artisan would understand what depths of penetration are required and are dependent upon the application, tissue type, area to be treated and severity of condition. Accordingly, the amount of energy used to treat the afflicted area would be attenuated based upon the disease or condition being treated.

The term "flexible elongate member" is well recognized in the art and is intended to refer to a hollow tube having at least one lumen. In general, a flexible elongate member is often termed a "catheter", a term which is well known in the art. The flexible elongate member has proximal and distal ends with at least one longitudinal lumen extending therebetween. The distal end can be open or closed as is known in the art. In one embodiment, the distal end of the flexible elongate member is open, thereby allowing a conductor, described *infra*, to protrude beyond the elongate member. In another embodiment, the distal portion of the elongate member is closed, thereby preventing a conductor from passing beyond the distal end of the elongate member.

Flexible elongate members, e.g., tubular catheters, can be formed from biocompatible materials known in the art such as cellulosic ethers, cellulosic esters, fluorinated polyethylene, phenolics, poly-4-methylpentene, polyacrylonitrile, polyamides, polyamideimides, polyacrylates, polymethacrylates, polybenzoxazole, polycarbonates, polycyanoarylethers, polyesters, polyestercarbonates, polyethers (PEBAX, polyether block amide), polyetherketones, polyetherimide, polyetheretherketones, polyethersulfones, polyethylene, polypropylene, polyfluoroolefins, polyimides, polyolefins, polyoxadizoles, polyphenylene oxides, polyphenylene sulfides, polysulfones, polytetrafluoroethylene, polythioethers, polytraizoles, polyurethanes, polyvinyls, polyvinylidene fluoride, silicones, urea-formaldehye polymers, or copolymers or physical blends thereof.

Preferably, the materials used to construct the flexible elongate member or the catheter end portion can be "transparent" materials, such as fluoropolymers. Suitable transparent materials include polyethylene, nylon, polyurethanes and silicone containing polymers, e.g., silastic. Suitable fluoropolymers include, for example, fluorinated ethylene propylene (FEP), perfluoroalkoxy resin (PFA), polytetrafluoroethylene (PTFE), and ethylene-tetrafluoroethylene (ETFE). Typically the diameter of the flexible elongate member is between about 0.5 millimeters and about 2.5 millimeters, preferably between about 0.75 millimeters and about 2.0 millimeters. The diameter of at least one inner lumen of the flexible elongate member is between about 0.25 millimeters and about 1.5 millimeters, preferably between about 0.5 millimeters and about 1.0 millimeters. The length of the flexible elongate member varies with the intended application and in generally between about 1 meter and about 3 meters in length. For cardiac applications the flexible elongate member is between about 2 meters and about 3 meters long.

The term "biocompatible" is well recognized in the art and as used herein, means exhibition of essentially no cytotoxicity while in contact with body fluids or tissues. "Biocompatibility" also includes essentially no interactions with recognition proteins, e.g., naturally occurring antibodies, cell proteins, cells and other components of biological systems.

The term "transparent" is well recognized in the art and is intended to include those materials which allow diffusion of energy through, for example, the flexible elongate member and/or deflection members. Preferred transparent materials do not significantly impede (e.g., result in losses of over 20 percent of transmitted energy) the energy being transferred from a conductor to the tissue or cell site. Suitable transparent materials include fluoropolymers, for example, fluorinated ethylene propylene (FEP), perfluoroalkoxy resin (PFA), polytetrafluoroethylene (PTFE), and ethylene-tetrafluoroethylene (ETFE).

The term "deflection member" is intended to include a supporting body which when placed under stress, will bend, deform or distort into a position different than that when no stress is applied. The deflection member includes distal and proximal ends. The deflection member has sufficient internal integrity such that stressing or tensing the deflection member material causes a physical body to which it is attached thereto to also bend, distort, or deform relative to the motion of the deflection member, e.g. a flexible elongation member.

The deflection member can have various configurations including, but not limited to, a solid unitary rod-like structure, a tube having an inner lumen, e.g. a catheter, a tube which has a fraction, e.g., one-half, one third, one quarter, of the distal portion removed in a longitudinal direction, or a tube comprising a plurality of deflection members, preferably two portions, e.g., a tube cut in half longitudinally, thereby forming an inner lumen. The deflection member can be coaxial with a flexible elongate member. In addition to being uniform in shape, the deflection member can also be formed into various shapes which attenuate the position of bend, deformation, or distortion.

For example, in one embodiment, the deflection member can have an hour glass shape, having at least one narrow portion relative to each base. One base of the hour glass is fixedly attached to the distal end of the elongate member and the proximal base of the hour glass extends to the proximal end of the elongate member. By varying the position of the narrow portion to the affixed distal portion of the hour glass relative to the proximal end of the elongate member, attenuation to the position of bending can be controlled. Generally, the narrow portion of the hour glass is positioned within about 0.5 cm and about 10 cm from the distal end of the hour glass and the distal end of the flexible elongate member. In addition, the narrow portion of the hour glass shape is approximately 0.1 to about 0.95, preferably about 0.5 the size of the base portions of the hour glass. Moreover, the hour glass shape can be part of a deflection member which has had a portion, such as a distal portion removed.

Advantageously, an hour glass configured deflection member affixed to a flexible elongate member provides an initial stiff distal end useful for pushing through tissue when no stress is applied to the proximal end of the deflection member. Once at or near the target tissue site, application of tension to the proximal end of the deflection member causes the initial stiff distal portion to bend becoming supple and floppy.

In another embodiment, the deflection member can be in the form of a tube or a portion of a tube, e.g., a tube with a portion of the distal end removed, which is tapered at the distal end. The tapered portion of the deflection member attenuates the position of the bend, deformation, or distortion and can be located at a position which provides one with the ability to bend the flexible elongated member at a desired position. For example, in one embodiment, the initial point of taper begins between about 10 cm and about 0.1 cm, inclusive, from the distal end of the deflection member, preferably between about 0.5 cm and between about 5 cm, inclusive, most preferably between about 1 cm and about 3 cm, inclusive. The tapered end can end form a point or have a width which is between about 0.05 mm and about 0.75 mm, inclusive , preferably between about 0.1 mm and about 0.5 relative to the base portion of the tapered portion.

In another embodiment, two or more deflection members are slidably engaged, e.g., interlocked, by methods known in the art and fixedly attached to the distal end of a flexible elongate member. For instance, two half-tubes, one with a male member and the other with a female member can be slidably engaged and fixedly attached a flexible elongate member. This type of arrangement provides the ability to manipulate the flexible elongate member and provides additional strength within the apparatus while the apparatus is being inserted through an artery or vein.

An advantage of a tapered deflection member lies in the ease of initial flexing when tension is applied to the proximal portion of the deflection member. An increase in tension results in increased resistance to bending, deforming or distorting the deflection member

further from the initial bend. It is to be understood that the present invention is not limited to one or two deflection members and one skilled in the art can readily appreciate various embodiments of deflection members within the scope of this invention.

An important advantage of the deflection members of the invention centers on the compatibility of the deflection member with the catheter body. The deflection member is typically constructed from the same or similar material as that of the catheter, thereby providing an integral match at attachment point(s). "Welding" of the deflection member to the catheter body provides an integral bond between the two members so that detachment does not occur. Additionally, as the deflection member is constructed from a polymeric material, heat is not appreciably transferred away from an anatomically important region to a site which does not require such treatment.

The term "fixedly attached" is intended to include those methods known in the art to attach a deflection member to an inner portion of a flexible elongate member at the distal portion of the flexible elongate member. Various means are known to those skilled in the art for fixedly attaching internal members to a flexibly elongate member. Such methods include thermal welding or glueing the two materials together to form a uniform seam which will withstand stresses placed upon the integral seam. In a preferred embodiment, the deflection member is "spot" welded, e.g., thermal, photochemical, sonically, e.g., ultrasound, or glued at the distal most portion of the deflection member to the distal end of the flexible elongate member. In another preferred embodiment, the distal end of the deflection member is affixed to the distal end of the elongate member which is itself a sealed, e.g., having a tip or a cap.

The term "control handle" is are recognized and is intended to include various means to manipulate the apparatus of the invention, including at least the flexible elongate member, the deflection member and the conductor, described *infra*. Various control handles useful with the present invention are commercially available, such as those

manufactured by Cordis Webster, Inc. 4750 Littlejohn St , Baldwin Park, CA, 91706. When used, the control handle applies tension, e.g., stress, to the proximate end of a deflection member, thereby causing the distal end of the deflection member to bend, distort or deform. As a consequence of this action, the flexible elongate member also bends, distorts or deforms in the same plane as the deflection member.

The term "conductor" is intended to include those apparatus which conduct energy in the form of an electrical current, ultrasound, microwave radiation, ultraviolet light, infrared radiation, or an optical wave guide such as a wave guide for coherent light, e.g., laser light. In a preferred embodiment, the conductor is an optical fiber. Typically, the energy transmitted is in the range between about 200 nanometers and about 10.5 micrometers. A preferred energy is coherent light, e.g., laser light, in the range between about 200 nm to about 2.4 μm, preferably between about 400 to about 3,000 nm, more preferably between about 805 and 1060 nm. Suitable lasers include diode lasers, Yag:Nd lasers and diode pumped solid state lasers. A particularly preferred AlGaAs diode array, manufactured by Optopower, Tucson, Arizona, produces a wavelength of 915 nm. Typically the conductor emits between about 2 to about 10 watts/cm of length, preferably between about 4 to about 6 watts/cm, most preferably about 4 watts/cm. In one embodiment, the conductor can extend beyond the distal end of the flexible elongate member.

The conductor transmits the energy from an energy source which is in communication with the proximal end of the conductor. Suitable energy sources are known in the art and produce the above-mentioned types of energy. The conductor is positioned within lumen formed by a flexible elongate member, a deflection member, a reflective material (described *infra*) or combinations thereof. The conductor can be slidably controlled within the lumen such that positioning of the conductor at the distal end of the flexible elongate member is readily achieved.

The conductor can have many forms known to those skilled in the art and can include a light diffuser or other appropriate configurations. Exemplary tips are described in U.S. Patents 5,042,980, 5,207,669, 5,253,312, 5,269,777, and those diffusion tips described in "Phototherapeutic Apparatus" by Edward L. Sinofsky, Lincoln S. Baxter and Norman Farr, and PCT Application No. PCT/US95/11246, International Publication No. WO 96/07451, published March 14, 1996, the teachings of all are incorporated herein by reference. A preferred tip is the diffusing laser tip available from Cardiofocus, Inc., West Yarmouth, MA 02673. The end of the tip can also be coated or coupled with an energy or light reflecting or deflecting material in order to prevent forward propagation of ablating energy.

The term "reflective material" is intended to encompass those materials which reflect energy, such as light, e.g., laser, ultraviolet, visible, or infrared light. Suitable materials are known in the art and include metal foils, preferably gold. Typically the reflective material has a thickness between about 0.05 mm and about 0.1 mm, inclusive.

The reflective material can be positioned proximate to, e.g., behind, the distal end of a conductor and the distal end of a deflection member, such that when the deflection member is tensed, the reflective material causes the energy to spread out in a convex manner. In one embodiment, both the flexible elongate member and the deflection member are transparent, the deflection member is partially cut away, tapered, or has an hour glass shape and the reflective material is positioned behind the deflection member and the conductor.

Alternatively, the reflective material can be positioned across from the distal end of the conductor and across from the deflection member, such that when the deflection member is tensed, the reflective material causes the energy to spread out in a concave manner, e.g., the energy is directed onto or into a specific target area. In one embodiment, both the flexible elongate member and the deflection member are transparent, the

deflection member is partially cut away, tapered, or has an hour glass shape and the reflective material is positioned across from the deflection member and conductor. Additionally, the reflective material can be located in between the deflection member and the flexible elongate member.

The terms "treat", "treatment" or "treating" are intended to include both prophylatic and/or therapeutic applications. The methods of the invention can be used to protect a subject from damage or injury caused by a disease, or can be used therapeutically or prophylactically treat the subject after the onset of the disease or condition.

The term subject is intended to include mammals susceptible to diseases, including one or more disease related symptoms. Examples of such subjects include humans, dogs, cats, pigs, cows, horses, rats and mice.

The term "tissue" is well recognized in the art and is intended to include extracorporeal materials, such as organs, e.g., mesentery, liver, kidney, heart, lung, brain, tendon, muscle etc., and corporeal materials, such as blood cells, e.g., red and white blood cells and extracellular components.

The term "disease" is associated with an increase of a pathogen within a subject such that the subject often experiences physiological symptoms which include, but are not limited to, release of toxins, gastritis, inflammation, coma, water retention, weight gain or loss, ischemia and immunodeficiency. The effects often associated with such symptoms include, but are not limited to fever, nausea, diarrhea, weakness, headache and even death. Examples of diseases which can be treated by the present invention include undesirable cell proliferation, bacterial infection, cancer, e.g., bladder, urethral, mammarian, ovarian cancer, or, ischemia, and benign prostatic hypertrophy or hyperplasia (BPH).

The language "undesirable cell proliferation" is intended to include abnormal

growth of cells which can be detrimental to a subject's physiological well being. Effects of undesirable cell proliferation can include the release of toxins into the subject, fever, gastritis, inflammation, nausea, weakness, coma, headache, water retention, weight gain or loss, immunodeficiency, death, etc. The undesired cells which proliferate can include cells which are either benign or malignant. Examples of undesirable cell proliferation include bacterial cell proliferation and aberrant cell division and/or proliferation of foreign cells, such as in cancer cells.

The terms "aberrant cell" or "aberrant tissues" as used herein, is well recognized in the art and is intended to include aberrant cell division and/or proliferation where cells are generated in excess of what is considered typical in physiologically similar environment, such as in cancers.

The language "control of undesirable cell proliferation" or "controlling undesirable cell proliferation" is intended to include changes in growth or replication of undesired cells or eradication of undesired cells, such as bacteria, cancer, or those cells associated with abnormal physiological activity. The language includes preventing survival or inhibiting continued growth and replication of an undesired cell. In one preferred embodiment, the control of the undesired cell is such that an undesired cell is eradicated. In another preferred embodiment, the control is selective such that a particular targeted undesired cell is controlled while other cells which are not detrimental to the mammal are allowed to remain substantially uncontrolled or substantially unaffected, e.g., lymphocytes, red blood cells, white blood cells, platelets, growth factors, etc.

The term "cancer" is well recognized in the art and is intended to include undesirable cell proliferation and/or aberrant cell growth, e.g., proliferation.

The invention is also directed to methods for ablating, coagulating, and/or phototherapeutically modulating a target tissue. The methods include introducing a

flexible elongate member into a predetermined tissue site with the flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween. The distal end of a deflection member is fixedly attached to the distal end of the flexible elongate member. The deflection member is manipulated longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend. A slidable conductor is positioned through the lumen proximately to the tissue site and energy is transmitted to the distal end of the elongate member through the conductor. The target tissue is ablated, coagulated and/or phototherapeutically modulated without damaging surrounding tissue. In one embodiment, the energy is transmitted through an energy transparent flexible elongate member. In another embodiment the energy is laser light. In still another embodiment, the energy is directed toward the target tissue by reflection from a reflective material behind or in front of the deflection member and/or the conductor.

The term "modulate" includes effect(s) targeted tissue(s) that prevent or inhibit growth of diseased tissue, which may ultimately affect the physiological well being of the subject, e.g., in the context of the therapeutic methods of the invention.

The present invention can also be described in certain embodiments as a method for ablating, coagulated and/or phototherapeutically modifying targeted tissue, such that the disease or condition is modified, e.g., eradicated, inhibited, or prevented. The method includes treating a target site with radiative or conductive energy to the target tissue in an amount effective to modulate the diseased tissue. This method can be used in cardiac tissue or heart tissue through application of energy to the endocardial surface, the epicardial surface or interstitial area of the heart. The method can also be applied to other organs, particularly the urethra, bladder, kidneys and bronchia. The method includes treating the organ with a source of energy such as laser, ultrasound, microwave, electrical current, to ablate, coagulate and/or phototherapeutically treat the target tissue site.

The invention is further directed to methods for treating trabecular tissue by ablation, coagulation or phototherapeutic processes. The methods include introducing a flexible elongate member proximate to trabecular tissue with the flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween. A deflection member is fixedly attached to the distal end of the elongate member and includes a proximal end and a distal end. The deflection member is manipulated longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend. A conductor is slidably positioned within the lumen, proximate to the trabecular tissue site. Energy is transmitted to the distal end of the elongate member through the conductor, such that the trabecular tissue is ablated, coagulated and/or phototherapeutically modulated without damaging surrounding tissue. The treatment can be performed prophylactically or therapeutically.

The term "trabecular" is well recognized in the art and is intended to include tissue, e.g., cardiac tissue, which is a spongy tissue often formed of bands and cords called *trabeculae* consisting of fibrous tissue, elastic fibers and muscle fibers.

The present invention is also directed to methods for treating or preventing atrial fibrillation by ablation, coagulation or phototherapeutic processes. The methods include introducing a flexible elongate member proximate to atrial tissue with the flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween. A deflection member is fixedly attached to the distal end of the elongate member and includes a proximal end and a distal end. The deflection member is manipulated longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend. A conductor is slidably positioned within the lumen, proximate to the atrial tissue site. Energy is transmitted to the distal end of the elongate member through the conductor, such that the atrial tissue is ablated, coagulated and/or phototherapeutically modulated without damaging surrounding tissue. The treatment can be performed prophylactically or therapeutically.

Atrial fibrillation and atrial flutter are abnormalities in the rhythm or rate of the heart beat. For an adult at rest, the heart normally beats between 60 and 80 beats per minute, but when atrial fibrillation occurs, the atria may beat irregularly and very rapidly between 350 and 600 times per minute. This causes the ventricles to beat irregularly in response as they try to keep up with the atria. Atrial flutter is similar to atrial fibrillation. The atrial contractions are less rapid, however, usually between 200 to 400 beats per minute, and are regular. Atrial flutter is often associated with a heart attack or may occur after heart or lung surgery. Atrial fibrillation often results from a myriad of heart conditions such as angina, tachycardia, heart attack, heart valve problems, and even high blood pressure. All of these conditions can cause stretching and scarring of the atria that interfere with the heart conduction system. The heart muscle can be weakened if episodes lasting several months or longer (with rapid heart rates) occur. Briefer episodes only cause problems if the heart rate is very fast or if the patient has a serious heart problem in addition to the atrial fibrillation.

FIGS. 1, 2 and 3 illustrate an apparatus of the invention 10 as a steerable catheter. Apparatus 10 includes a flexible elongate member 12 having a proximal end 14 (not shown), a distal end 16 and a lumen 18. Apparatus 10 also includes a deflection member 20 having a proximal end 22 (not shown) a distal end 24 and lumen 26. Deflection member is U-shaped or trough like, e.g., a tube cut in half horizontally, and formed to fit within lumen 18 of flexible elongate member 12. Distal end 24 of deflection member 20 is affixed to the distal end 16 of flexible elongate member 12 via weld 30; preferably deflection member 20 is affixed to a sealed or capped distal end or tip (not shown) of flexible elongate member 12.

Apparatus 10 further includes conductor 32 slidably disposed within lumen 18 of the flexible elongate member 12 and, optionally, a reflectance fiber 80 (described *infra*). Apparatus 10 is connected to control handle 28 (not shown) which provides maneuverability and positioning. Conductor 32 is further connected to energy source 34,

e.g., a laser source.

The devices described throughout the application can be used for treating, e.g., ablating, coagulating and/or phototherapeutically treating endocardial surfaces which promote arrhythmias or other disease states or conditions. For example, atrial therapies can be performed by inserting an apparatus of the invention 10 into the femoral vein. Flexible elongate member 12 having deflection member 20 is guided through the inferior vena cava, and into the right atrium, and if required, it is guided into the left atrium via atrial septal puncture. Left ventricular treatment can be performed by inserting flexible elongate member 12 having deflection member 20 into the femoral artery. Flexible elongate member 12 is guided through the iliac artery, the aorta, through the aortic valve and into the left ventricle. Alternatively, an approach can be used entering the left atrium transeptally. Once deflection member 20 is proximate to the tissue ablation site, deflection member 20 can be flexed or tensed via control handle 28 to more precisely position distal end 16 of flexible elongate member 12. In either example, conductor 32 is pushed through flexible member 12 via lumen 18 to a position proximate to the tissue ablation site.

It should be appreciated that flexible elongate member 12 can have electrodes (not shown) situated about the outer surface. These electrodes include wires which are in communication with a computer (not shown). The electrodes record the electrical potentials in the tissues, e.g., myocardial tissue. The computer collects the information from the electrodes and displays them on an isochronal map on a computer screen, depicting the selected tissue area, e.g., the wall of the chamber of a heart. For example, the computer can be used to derive activation times, the distribution and waveforms of potential recorded by the electrodes. The operator can utilize the isochronal map to identify area(s) where ablation energy is required. Optionally, the computer can operate energy source 34 to provide sufficient energy to ablate the diseased tissue area. Once the distal end of conductor 32 is proximate to the electrode selected by the operator, the computer can calculate the energy required to treat the afflicted area and apparatus 10 can

be removed. Suitable electrode configurations, type of wire, location of wires, and spacing about the flexible member are described in U.S. Patent No. 5,411,025, 5,772,590 and 5,782,899, the teachings of which are incorporated herein by reference.

FIGS. 4, 5 and 6 illustrate another aspect of apparatus 10 as a steerable catheter. In FIGS. 4, 5 and 6, deflection member 36 is a unitary solid rod-like material which is fixedly attached to distal end 16 of flexible elongate member 12 via weld 30 as described above. Unitary solid deflection member 36 is in communication with control handle 28 (not shown).

FIGS. 7, 8 and 9 illustrate yet another aspect of apparatus 10 as a steerable catheter. Apparatus 10 includes a first deflection member 20 and a second deflection member 27, both fixedly attached to flexible elongate member 12 via welds 30. Second deflection member includes proximal end 38 and distal end 39. Apparatus 10 further includes conductor 32 slidably located within lumen 18 and 40 formed by deflection members 20 and 37 and flexible elongate member 12. Both deflection members 20 and 37 are in communication with control handle 28 (not shown). It can be envisioned by one skilled in the art that a plurality of deflection members 20 could be positioned about the interior of flexible elongate member 12 and connected to control handle 28 for added control and manipulation of apparatus 10.

FIGS. 10 and 11 illustrate still another aspect of apparatus 10 as a steerable catheter. Apparatus 10 includes an hour glass-like deflection member 20 fixedly attached to distal end 16 of flexible elongate member 12 via weld 30 and conductor 32 located within the lumen formed by the hour glass shaped deflector 20 member and/or the flexible elongate member 12. Hour glass deflection member 20 includes narrow portion 42 in comparison to base portions 43 of the hour glass, providing an area which bends when tension is applied by control handle 28 (not shown).

FIGS. 12, 13 and 14 illustrate yet another aspect of apparatus 10 as a steerable catheter. Apparatus 10 includes tapered deflection member 44 fixedly attached to distal end 16 of flexible elongate member 12 via weld 30 and a conductor 32 located within lumen formed by tapered deflection member 44 and/or the flexible elongate member 12. Tapered deflection member 44 includes a cone like portion in comparison to base portion 43 of the remaining portion of deflection member 20, providing an area which bends when tension is applied by control handle 28 (not shown).

FIGS. 15, 16 and 17 represent still another aspect of apparatus 10 as a steerable catheter. Apparatus 10 includes a deflection member 20 which has a section removed 41 proximate to distal end 24 of deflection member 20. Conductor 32 is slidably located within lumen 18 and/or 26 formed by deflection member 20 and/or flexible elongate member 12. Distal end 24 of deflection member 20 which remains is fixedly attached to distal end 16 of flexible elongate member 12 via weld 30. Application of tension to the portion of deflection member 20 which remains distally attached to distal end 16 causes flexible elongate member 12 to bend at approximately one half the distance of the portion which was removed from deflection member 20.

FIGS.18, 19 and 20 represent still yet another embodiment of apparatus 10 as a steerable catheter as shown in FIGS. 2 through 18. In this example, apparatus 10 further includes a reflective material 46 attached to flexible elongate member 12 and a cut away deflection member 20 with removed section 41. The portion of distal end 24 of deflection member 20 which remains, is fixedly attached to distal end 16 of flexible elongate member 12 via weld 30. Distal end 24 of deflection member 20 which remains, is positioned proximate to reflector material 46, e.g., in front of reflector material 46, and conductor 32 is slidably positioned in front of both reflector material 46 and the remaining distal end section 24 of deflection member 20. Energy waves 48 emitted via slidable conductor 32 are transformed into reflected energy waves 50 and focused on diffuse area 52 as tension is applied to distal end 24 of deflection member 20. In one embodiment flexible elongate

member 12 is energy transparent. In a preferred embodiment, both flexible elongate member 12 and deflective member 20 are energy transparent.

FIGS. 21, 22 and 23 represent still yet another embodiment of apparatus 10 as a steerable catheter as shown in FIGS. 2 through 18. In this example, apparatus 10 further includes reflective material 46 attached to flexible elongate member 12 and a cut away deflection member 20 with removed section 41. The section of distal end 24 of deflection member 20 which remains, is fixedly attached to distal end 16 of flexible elongate member 12 via weld 30. Distal end 24 of deflection member 20 which remains, is positioned across from reflector material 46, e.g., apart from reflector material 46, and conductor 32 is slidably positioned in front of both reflector material 46 and the remaining distal end 24 of deflection member 20. Energy waves 48 emitted via slidable conductor 32 are transformed into reflected energy waves 50 and directed on focused area 54 as tension is applied to distal end 24 of deflection member 20. In a preferred embodiment, both flexible elongate member 12 and deflective member 20 are energy transparent.

FIG. 24 represents another embodiment of apparatus 10 as a steerable catheter as shown in FIGS. 2 through 18. As can be seen in FIG. 24, deflection member 20 is partially cut away for a portion of its distal length. The cut away portion can rotate about the longitudinal axis of deflection member 20 at positions A and B, for example, as shown in FIGS. 24 A and B. In one aspect, deflection member 20 is corkscrew shaped, e.g., a helix. FIG. 24 C at position C depicts a portion of deflection member 20 which forms a solid tube immediately prior to the cut away portion which forms the helical portion of deflection member 20. In FIG. 24, deflection member 20 can be precoiled during assembly to attain a desired number of coils, e.g., 1, 2, 3, 4, 5 or more. It should be understood that a conductor 32, a reflectance fiber 80, and reflective material 46, or combinations thereof, can be further included in FIG. 24 as described throughout the specification.

FIG. 25 represents still another embodiment of apparatus 10 as a steerable catheter as shown in FIGS. 2 through 18. In FIG. 25, apparatus 10, deflection member 20 is partially cut away for a portion of its intermediate length. For example, cut away portion A, depicted in FIG. 25 A, flexes in the horizontal plane. Cut away portion B of deflection member 2 , shown in FIG. 25 B, flexes in the vertical plane. Material is removed from deflection member 20 at portion A to achieve a first bend, then deflection 20 returns to a whole tube at section D as shown in FIG. 25 D, returning to a partial tube in section B. In one embodiment, material is removed in cut away portion B at a 90 degree angle relative to cut away portion A. FIG. 25 C, depicted at position C, shows that deflection member 20 can form a solid tube immediately prior to the cut away portion which forms portion A. It should be understood that a conductor 32, a reflectance fiber 80, and reflective material 46, or combinations thereof, can be further included in FIG. 25 as described throughout the specification.

The length and diameter of the flexible elongate member 12 are not critical and may vary according to the application. For cardiovascular applications, a length of about 40 to 48 inches and an outer diameter of about 0.1 inch (7 or 8 French is preferred). Preferably flexible elongate member 12 is formed of a transparent material.

In preferred embodiment, deflection member 20 is formed of a transparent material, e.g., a fluoropolymer.

In another preferred embodiment, conductor 32 is a light transmitting fiber, e.g., fiberoptic.

FIG. 26 illustrates an apparatus of the invention 10 as a steerable catheter. Apparatus 10 includes a flexible elongate member 12 having a proximal end 14 (not shown), a distal end 16 and a lumen 18. Apparatus 10 also includes a deflection member 20 having a proximal end 22 (not shown) a distal end 24 and lumen 26. Deflection

member 20 is formed as described above and formed to fit within lumen 18 of flexible elongate member 12. Distal end 24 of deflection member 20 is affixed to the distal end 16 of flexible elongate member 12 via multiple welds 30. Multiple welds about deflection member 20 provides a means for causing the apparatus to be deflected in an x, y plane, y, z plane, or x, z plane. It is understood that apparatus 10 can further include reflective material 46, as described above, and can be energy transparent.

FIG. 27 depicts use of an apparatus 10 of the invention for treatment of an atrium wall 56. Apparatus 10 can be manipulated by one or more deflection member(s) 20 welded within flexible elongate member 12. Energy conductor 32 can be slidably positioned within lumen 18 proximate to atrium wall 56. In a preferred embodiment, conductor 32 is equipped with a light diffuser 58 to provide light energy to a targeted site.

FIG. 28 depicts still another embodiment of the invention where apparatus 10 can be manipulated by two or more deflection member(s) 20 which have a male and a female joint which allows the deflection members to be slidably positioned relative to each other. Deflection members 20 are welded 30 to distal end 16 of flexible elongate member 12.

It should be understood by one of skill in the art that reflectance fiber 80 can be slidably positioned within apparatus 10, as depicted by FIGS. 1-28, proximate to conductor 32. Alternatively, reflectance fiber 80 can be affixed to an interior lumen of apparatus 10.

In the present invention, reflective feedback is used to monitor the state of coagulation, ablation and/or phototherapeutic processes of the treatment site so as to allow an optimal dose by either manipulation of the energy level or exposure time, or by controlling the sweep of energy across an exposure path.

Reflectance changes can also be employed by a control means in the present invention to adjust or terminate laser operation.

In another aspect of the invention, a real-time display means can be incorporated into a surgical microscope or goggles worn by a clinician during the procedure to provide a visual display of the state of tissue coagulation simultaneously with the viewing of the surgical site. The display can reveal reflectance values at one or more specific wavelengths (preferably, chosen for their sensitivity to the onset and optimal state of tissue modification), as well as display a warning of the onset of tissue carbonization.

In one method, according to the invention, application of laser to a biological structure(s) while the reflectance of light from the irradiated site is monitored. Changes in scattering due to coagulation, ablation, phototherapetuic effects or crosslinking of the tissue will cause a reflectance change. In addition, dehydration due to laser exposure also affects the site's reflection. The reflectance can be monitored in real-time to determine the optimal exposure duration or aid as visual feedback in the timing used in sweeping the energy across the treatment site during the procedure.

In FIG. 29, a schematic block diagram of a laser tissue treatment system 60 is shown, including a laser 62, power supply 64, controller 66 and reflectance monitor 68. The system further includes optical apparatus 10, and, optionally, illumination source 70, display 72 and/or tuner 74. In use, the output of laser 62 is delivered, preferably via optical apparatus 10, to treatment site 76 to phototherapeutically treat selected tissue. As the laser beam irradiates treatment 76 the biological tissue of the site is coagulated, ablated and/or phototherapeutically treated. The degree of treatment is determined by the reflectance monitor 68, which provides electrical signals to controller 66 in order to control the procedure. The reflectance monitor 68 receives light reflected by the site from a broadband or white light illumination source 70 via fiber 71 and/or from laser 62. In addition to controlling the laser operation automatically, the reflectance monitor 68 and/or controller 66 can also provide signals to a display 72 to provide visual and/or audio feedback to the clinical user. Optional tuner 74 can also be employed by the user (or automatically controlled by controller 66) to adjust the wavelength of the annealing

radiation beam.

FIG. 30 is a more detailed schematic diagram of a reflectance monitor 68, including a coupling port 78 for coupling with one or more fibers 80 to receive reflectance signals. A preferred reflectance fiber is a 100 micron diameter silica pyrocoat fiber from Spectran (Spectran, Connecticut, part number CF04406-11). The reflectance monitor 68 can further include a focusing lens 82 and first and second beam splitting elements 84 and 86, which serve to divide the reflected light into 3 (or more) different beams for processing. As shown in FIG. 28, a first beam is transmitted to a first optical filter 88 to detector 90 (providing, for example, measurement of reflected light at wavelengths shorter than 0.7 micrometers). A second portion of the reflected light signal is transmitted by beam splitter 86 through a second optical filter 92 to detector 94 (e.g., providing measurement of light at wavelengths shorter than 1.1 micrometers). Finally, a third portion of the reflected light is transmitted to photodetector 96 (e.g., for measurement of reflected light at wavelengths greater than 1.6 micrometers). Each of the detector elements 90, 94 and 96 generate electrical signals in response to the intensity of light at particular wavelengths.

The detector elements 90, 94 and 96 preferably include synchronous demodulation circuitry and are used in conjunction with a modulated illumination source to suppress any artifacts caused by stray light or the ambient environment. (It should be apparent that other optical arrangements can be employed to obtain multiple wavelength analysis, including the use, for example, of dichroic elements, either as beam splitters or in conjunction with such beam splitters, to effectively pass particular wavelengths to specific detector elements. It should also be apparent that more than three discreet wavelengths can be measured, depending upon the particular application.) The signals from the detector elements can then be transmitted to a controller and/or a display element (as shown in FIG. 29).

In the controller, signals from the reflectance monitor are analyzed to determine

the degree of coagulation, ablation and/or phototherapeutic effect(s) which is occurring in the biological tissue exposed to the laser radiation. Typically, such treatment is performed for 100 seconds or less. Such analysis can generate control signals which will progressively reduce the laser output energy over time as a particular site experiences cumulative exposure. The control signals can further provide for an automatic shut-off of the laser when the optimal state of treatment has been exceeded and/or the onset of carbonization is occurring.

In use, the apparatus of the present invention can be employed to analyze the degree of treatment by comparing the reflectance ratios of a site at two or more wavelengths. Preferably, intensity readings for three or more wavelength ranges are employed in order to accurately assess the degree of treatment and to ensure that the optimal state is not exceeded. The particular wavelengths to be monitored will, of course, vary with the particular tissue undergoing treatment. Although the tissue type (e.g., blood-containing tissue or that which is relatively blood-free) will vary, the general principles of the invention, as disclosed herein, can be readily applied by those skilled in the art to diverse procedures in which the phototherapeutic treatment of biological materials is desired.

Those skilled in the art will know, or be able to ascertain, using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. These and all other equivalents are intended to be encompassed by the following claims. All publications and references cited herein including those in the background section are expressly incorporated herein by reference in their entirety.